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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,834	09/29/2000	Michael Z. Gilman	APBI-P04-340	4232

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ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/676,834</b>	Applicant(s) <b>Gilman</b>
	Examiner <b>William Sandals</b>	Art Unit <b>1636</b>



-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on Sep 29, 2000
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1-23 are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some\* c) None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

*PJZ  
DWT/CO*

**DETAILED ACTION**

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding thrombospondin gene and a method of use of the cell, classified in class 435, subclass 455.
  - II. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding angiostatin gene and a method of use of the cell , classified in class 435, subclass 455.
  - III. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding endostatin gene and a method of use of the cell, classified in class 435, subclass 455.
  - IV. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding angiostatin-endostatin fusion gene and a method of use of the cell, classified in class 435, subclass 455.

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- V. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding angiopoietin gene and a method of use of the cell, classified in class 435, subclass 455.
- VI. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding soluble VEGF gene and a method of use of the cell, classified in class 435, subclass 455.
- VII. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding dominant negative VEGF gene and a method of use of the cell, classified in class 435, subclass 455.
- VIII. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding anti VEGF antibody gene and a method of use of the cell, classified in class 435, subclass 455.
- IX. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding Tie2/Tek receptor gene and a method of use of the cell, classified in class 435, subclass 455.
- X. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding 16kd

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fragment prolactin gene and a method of use of the cell, classified in class 435, subclass 455.

- XI. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding tumor specific antigen gene and a method of use of the cell, classified in class 435, subclass 455.
- XII. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding  $\beta$  interferon gene and a method of use of the cell, classified in class 435, subclass 455.
- XIII. Claims 1-5, 14-15 and 17-20, drawn to a cell containing a DNA encoding a receptor protein with a ligand binding domain and a DNA encoding cytokine gene and a method of use of the cell, classified in class 435, subclass 455.
- XIV. Claims 12 and 13, drawn to a recombinant virus, classified in class 435, subclass 320.1.
- XV. Claim 21, drawn to a method of treating cancer, classified in class 514, subclass 44.
- XVI. Claim 22, drawn to a method of treating multiple sclerosis, classified in class 514, subclass 44.
- XVI. Claim 23, drawn to a method of treating HIV, classified in class 514, subclass 44.

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2. The above groups contain the same claim in more than one group. Upon the election of a group, the claim will be examined as it pertains to the subject matter of the elected group.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I-XIII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the invention of Group I has separate utility such as expression of a thrombospondin gene, the invention of Group II has separate utility such as expression of a angiostatin gene, the invention of Group III has separate utility such as expression of a endostatin gene, the invention of Group IV has separate utility such as expression of a angiostatin-endostatin fusion gene, the invention of Group V has separate utility such as expression of a angiopoietin gene, the invention of Group VI has separate utility such as expression of a soluble VEGF gene, the invention of Group VII has separate utility such as expression of a dominant negative VEGF gene, the invention of Group VIII has separate utility such as expression of a anti VEGF antibody gene, the invention of Group IX has separate utility such as expression of a Tie2/Tek receptor gene, the invention of Group X has separate utility such as expression of a 16kd fragment prolactin gene, the invention of Group XI has separate utility such as expression of a tumor specific antigen, the invention of Group XII has separate utility such as expression of a  $\beta$  interferon gene, the invention of Group I has separate utility such as expression of a cytokine gene. See MPEP § 806.05(d).

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4. The inventions of Groups 1-XIII, XV-XVII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of the recombinant virus of Group XIV is biologically, physically, chemically and patentably distinct from the cells and methods of use of groups I-XIII and the methods of treatment of groups XV-XVII.

5. The inventions of Groups XV-XVII and are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods of treatment are drawn to biologically, physically, chemically and patentably distinct cancer (group XV), multiple sclerosis (group XVI) and HIV (group XVII) diseases.

6. Because these inventions are distinct for the reasons given above and the search required for each of Group I through Group XVII is not required for each of the other Groups I-XVII, restriction for examination purposes as indicated is proper.

7. Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the ligand binding domains of claim 3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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8. Claim 6 is generic to a plurality of disclosed patentably distinct species comprising the ligand binding domains of claim 8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

9. Claim 9 is generic to a plurality of disclosed patentably distinct species comprising the ligand binding domains of claim 10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### ***Conclusion***

12. Certain papers related to this application are **welcomed** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If

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applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

March 24, 2002